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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,784	07/02/2003	Ray C. Wasiclewski	ORW01-GN004	5434

30074 7590 07/19/2007
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CINCINNATI, OH 45202-3957

EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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07/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/612,784

Applicant(s)

WASIELEWSKI, RAY C.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,14,15,27-32,37-39,109 and 110 is/are pending in the application.
- 4a) Of the above claim(s) 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 14, 15, 27-32, 37, 109 and 110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 7/11/07 have been fully considered.

Regarding the 102/103 rejections in view of Kuber (DE 19716051, applicant submitted), the Examiner position is believed to be clearly stated to one having ordinary skill in the art in the grounds of rejection below.

Regarding applicant's statement, "*[I]n fact, the Office action itself concludes that those skilled in the art would have wanted scar tissue formation, which is in direct contrast with what Applicant is claiming*" is contradicting what applicant previous thought. See cancelled claim 19 which read:

19. (ORIGINAL) The prosthetic device of claim 1, wherein the augment material is adapted to be substantially absorbed by a patient's body after implantation and to be substantially replaced by scar tissue.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-6, 14, 15, 27-32, 37, 109, and 110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, "*wherein the augment material does not form scar tissue*" is interpreted as functional language and is ambiguous. Most foreign material, whether it is absorbable or non-absorbable, can produce scar tissue around it. Applicant's claim 5

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claims PLLA as does Kuber; the same materials should behave the same when implanted. The intent of this limitation is unclear.

Claim 1, 27, and 109, "an acetabular liner having mating features to releasably engage corresponding mating features of an acetabular cup" is ambiguous as to what elements are being claimed.

Claim 110, "acetabular liner including at least one circumferentially oriented recess to releasably engage a corresponding projection of an acetabular cup" is ambiguous as to what elements are being claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-6, 14, 15, 27-32, 37, 109, and 110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1, "*wherein the augment material does not form scar tissue*" is new matter. Most foreign material, whether it is absorbable or non-absorbable, can

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produce scar tissue around it. Applicant's claim 5 claims PLLA as does Kuber; PLLA can form scar tissue.

Claim 1, 27, and 109, "an acetabular liner having mating features to releasably engage corresponding mating features of an acetabular cup" is new matter.

Claim 110, "acetabular liner including at least one circumferentially oriented recess to releasably engage a corresponding projection of an acetabular cup" is new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-6, 14, 15, 27-32, 37, 109, 110 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuber (DE 19716051, applicant submitted).

1. (CURRENTLY AMENDED) A prosthetic device for use with a hip replacement prosthesis that includes an acetabular cup assembly to be fastened to a patient's pelvis and a femoral stem to be fastened to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, the prosthetic device comprising:

an acetabular liner B having mating features (**35 U.S.C. 102(b)** see figure 4, any of the tab-like elements or figure 3, the indent elements) to releasably engage corresponding mating features of an acetabular cup permanently mounted to the patient's pelvis; and

a semiannular augment A to be mounted approximate to a rim of an acetabular assembly liner of a hip replacement prosthesis, wherein the semiannular augment assists in improving stability of a ball joint type coupling by increasing the height of a portion of the rim of the acetabular liner, at least temporarily, between the acetabular assembly liner and a femoral stem of the hip replacement prosthesis while allowing rotational and angular movement between the acetabular cup assembly and the femoral stem;

the semiannular augment being formed from an augment material comprising at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials; and

wherein the augment material does not form scar tissue (note Kuber and applicant teach PLLA, see at least applicant's claim 5).

Regarding at least claim 1, however, Kuber fails to teach the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent. It would have been obvious to one having ordinary skill in the art to have utilized any of the known bioresorbable materials or combinations thereof and to include an agent to promote scar tissue, clotting, and antibacterial agent for their known biocompatibility and characteristic such as preventing a bacterial infection.

In the alternative, under 35 U.S.C. 103(a): Regarding the mating features to releasably engage corresponding mating features of an acetabular cup, these features are well known in the art; see Mikhail (56,549,701) teaching a liner 12 having mating features 34 and 30. Note Mikhail teaches the liner can be implanted into an acetabular cup 14 as shown in figure 1 or directly implanted into the acetabulum as shown in figure 2. It would have been obvious to one having ordinary skill in the art to have used any mating features known in the art such as those taught by Mikhail on the plastic liner B of Kuber to anchor the liner in a cup preventing relative motion which produces wear debris.

Regarding claims 2 and 29, see fastener C made of PLLA.

Regarding claims 4 and 30, fastener C is a screw.

Claims 6 and 32 only further defines the ECMs.

Regarding at least claim 14, the screw is integrated.

Regarding at least claim 15, applicant's specification teaches various fastening means including screws; see paragraph 0032 and 4. At the time the invention was

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made, it would have been obvious to a person of ordinary skill in the art to snap-on retention members. Applicant has not disclosed that said configuration provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either screws or a snap-on configuration. Therefore, it would have been obvious to one of ordinary skill in the art to modify Kuber to obtain the invention as claimed.

Regarding claim 27, this claim is rejected under 102/103 not requiring an agent to promote scar tissue, clotting, and antibacterial agent as required in claim 1.

Regarding the limitation that the augment material does not form scar tissue, Kuber teaches the same material as applicant.

Regarding claim 37, see reasoning above.

Regarding claim 109, it would have been obvious to one having ordinary skill in the art to have made the augment of Kuber into multiple separate parts or sized smaller such that the surgeon could place the augment(s) only where deemed necessary for the patient introducing less foreign matter into said patients body. MPEP 2144 states: The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. See MPEP 2144.04 IV (A) Changes in size/proportion and (C) Making Separable.

Claim 110 is rejected under 102/103, see reasoning above.

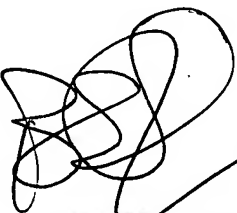
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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BRUCE SNOW
PRIMARY EXAMINER